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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,004	06/05/2002	Carlo Ghisalberti	3006-0044	6429

7590 06/13/2003

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EXAMINER
LAMM, MARINA

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 06/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	10/088,004	GHISALBERTI, CARLO	
	Examiner	Art Unit	
	Marina Lamm	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *11-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 11-29 are pending in this application filed 6/5/02. Claims 1-10 have been cancelled by a preliminary amendment. Claims 11-119 are directed to a topical composition comprising a conjugated linoleic acid or a derivative thereof ("CLA"). Claims 20-29 are directed to a method of treating or preventing fatty deposits and cellulite comprising topically administering a CLA or a composition comprising CLA.

Claim Objections

1. Claims 18 and 28 are objected to because of the following informalities: the term "theophylline" is misspelled. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 20-29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of *treating* fatty deposits and cellulite, does not reasonably provide enablement for a method of *preventing* fatty deposits and cellulite. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). They include: (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or unpredictability of the art, (4) the relative skill of those in the art, (5) the breadth of the claims,

(6) the amount or direction or guidance presented, (7) the presence or absence of working examples, and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the Examiner's position that one skilled in the art could not practice the invention as claimed without undue experimentation.

(1) the nature of the invention

The invention provides a method for preventing fatty deposits and cellulite comprising topically applying to the skin a CLA or a composition comprising CLA.

(2) the state of the prior art

Prior art teaches that topically applied CLA esters have an ability to "reduce body fat". See WO 99/32105, at p. 9, lines 3-14. Further, WO 00/01351 teaches a topical composition for "promoting cellulite removal" comprising CLA. See Example 12. However, prior art does not teach *prevention* of fatty deposits and cellulite by topical application of CLA or CLA-containing composition.

(3) the predictability or unpredictability of the art

The "predictability or lack thereof" in the art refers to the ability of one skilled in the art to extrapolate the disclosed or known results to the claimed invention. If one skilled in the art can readily anticipate the effect of a change within the subject matter to which the claimed invention pertains, then there is predictability in the art. On the other hand, if one skilled in the art cannot readily anticipate the effect of a change within the subject matter to which that claimed invention pertains, then there is lack of predictability in the art. Accordingly, what is known in the art provides evidence as to the question of predictability. See MPEP 2164.03. In this case, the prior art lacks knowledge in regards to the prevention of the formation of fatty

deposits and cellulite by topical application of CLA or CLA-containing composition. Although, WO 99/32105 suggests that CLA esters have an ability to "reduce body fat", it does not teach that such reduction of body fat will prevent the formation of fatty deposits and cellulite. Thus, one skilled in the art cannot readily anticipate this effect based on the prior art teachings. Accordingly, the unpredictability of the art is high.

(4) the relative skill of those in the art

The relative skill of the those in the art is high.

(5) the breadth of the claims

The claims are very broad. They encompass prevention of formation of fatty deposits and cellulite by topically applying any composition containing CLA.

(6) the amount or direction or guidance presented

The instant specification discloses compositions and methods for the *treatment* of fatty deposits and cellulite by topically applying a composition containing CLA. All the examples in the specification are directed to the treatment of said conditions. Thus, the specification is enabling for such methods and compositions. The specification does not provide sufficient guidance to allow one skilled in the art to use the claimed composition for the *prevention* of the formation of said fatty deposits and cellulite. There is insufficient guidance and objective evidence in the art that would indicate that CLA will be able to prevent fatty deposits and cellulite formation. The fact that CLA was demonstrated to be an effective agent for the treatment of fatty deposits and cellulite, is not an evidence that it will be effective in the prevention of these conditions.

(7) the presence or absence of working examples

As stated above, all the examples in the specification are directed to the treatment of said fatty deposits and cellulite rather than the claimed prevention. The specification does not provide any working examples that would indicate the claimed composition containing CLA is able to prevent fatty deposits and cellulite formation.

(8) the quantity of experimentation necessary

The specification provides insufficient guidance with regard to the claimed method and contains no working examples and no evidence which would allow one of skill in the art to predict the efficacy of the claimed method of prevention with a reasonable expectation of success. Moreover, the nature of the invention and the state of prior art have not provided any reasonable expectation of success in the prevention of fatty deposits and cellulite formation. For the above reasons, it appears that one skilled in the art could not practice the invention with the claimed breadth without an undue amount of experimentation.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 29 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "method according to claim 21 further comprises a vanadium compound" renders Claim 29 indefinite. The recitation is confusing because it merely recites an ingredient of the composition and fails to recite any specific positive method steps and limitations which contribute to the improvement in the claimed method.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

7. Claims 11, 13, 15, 20, 21, 23 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Millis (WO 99/32105) supplied by the Applicant.

Millis teaches topical cosmetic compositions in the form of lotions, creams, gels, sprays, etc. containing CLA esters and a carrier. See pp. 4-5; Claims 1-9. Millis teaches topically applying the compositions to the skin. See p. 5, lines 24-30. With respect to Claims 20-29, Millis teaches that CLA esters have an ability to "reduce body fat", and, therefore, the CLA-containing topical compositions can be useful for reducing body fat. See p. 9, lines 3-15.

Thus, Millis teaches each and every limitation of Claims 11, 13, 15, 20, 21, 23 and 25.

8. Claims 11-13, 15, 20-23 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by either Bryce-Smith (WO 98/17269), supplied by the Applicant, or Remmereit (WO 99/26588).

Bryce-Smith teaches topical compositions containing zinc salts of CLA. See Abstract. The compositions may be in the form of creams and may comprise at least 50% of the salt. See pp. 4, 5. The compositions of Bryce-Smith are topically administered to the skin. See Examples B-J. With respect to Claims 20-23 and 25, the topical application of the compositions of Bryce-Smith will inherently result in the reducing of fatty deposits and cellulite. Since the method step is the same, the result will inherently be the same.

Remmereit teaches topical cosmetic compositions containing free and derivatized forms of CLA such as esters. See Abstract; p. 7, lines 19-35. "Uptake of CLA into cellular lipids is associated with ... lipid repartitioning, and other beneficial physiological effects." See p. 7, lines 2-5. The compositions of Remmereit make the skin more supple, pliant and moisturized. See p. 15, lines 17-22. Remmereit exemplifies creams and lotions containing 6-8% of CLA. See p. 17. With respect to Claims 20-23 and 25, the topical application of the compositions of Remmereit will inherently result in the reducing of fatty deposits and cellulite. Since the method step is the same, the result will inherently be the same.

Thus, Bryce-Smith and Remmereit, each teaches every limitation of Claims 11-13, 15, 20-23 and 25.

9. Claims 11-13, 15-18, 20-23 and 25-28 are rejected under 35 U.S.C. 102(a) as being anticipated by Kirby et al. (WO 00/01351), supplied by the Applicant, or under 35 U.S.C. 102(e) as being anticipated by Kirby et al. (US 6,444,234).

Kirby et al. teach an aqueous cream formulation for promoting cellulite removal containing CLA and theophilline. See Example 12. Further, Kirby et al. teach an aqueous based weight reducing formula containing 1.2% of CLA in combination with caffeine and

theophilline. See Example 10. The compositions of Kirby et al. are applied to the skin. See Abstract.

Thus, Kirby et al. teach each and every limitation of Claims 11-13, 15-18, 20-23 and 25-28.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 19 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Millis or Bryce-Smith or Remmereit or Kirby et.al. in view of Nechay (WO 90/12563).

Millis or Bryce-Smith or Remmereit or Kirby et al. applied as above. Neither reference teach a vanadium compound of the instant claims. However, Nechay teaches that topical vanadium formulations improve cosmetic appearance, rejuvenate skin, alleviate wrinkles, enhance tissue structure and heal damaged tissue. See Abstract; p. 2, lines 1-24; p. 24, lines 1-17; Examples. Vanadium salts have very low toxicity and skin irritation levels. See p. 12, lines 5-9. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the topical cosmetic or dermatological compositions of either Millis, Bryce-Smith, Remmereit or Kirby et al. such that to include the vanadium compounds of Nechay. One having ordinary skill in the art would have been motivated to do

this to obtain topical compositions which enhance tissue structure, heal damaged tissue and rejuvenate skin without causing toxicity or skin irritation as suggested by Nechay.

12. Claims 12 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Millis.

Millis applied as above. Millis does not explicitly teach the claimed CLA concentration of 0.5-70%. However, Millis teaches that his compositions contain CLA esters and a carrier as discussed above. The lotion carrier may comprise from about 1% to about 20% of an emollient and from about 50% to about 90% of water. See p. 7, lines 3-5. The cream carrier may comprise from about 5% to about 50% of an emollient and from about 45% to about 85% of water. See p. 7, lines 6-9. The compositions of Millis may additionally comprise ancillary components such as fragrance, wax, coloring, etc. See p. 7, lines 19-26. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ CLA in the claimed concentrations in view of the reference's teaching that the carrier may comprise from about 50 to about 90% of the composition.

13. Claims 14 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kirby et al. in view of Pariza et al. (US 5,208,356).

Kirby et al. applied as above. Kirby et al. does not explicitly teach the claimed salts of CLA. However, Pariza et al. teach that sodium and potassium salts of CLA are water-soluble and non-toxic. See col. 2, lines 23-35. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the aqueous topical compositions of Kirby et al. such that to employ sodium or potassium salts of CLA. One having ordinary skill in the art would have been motivated to do this to incorporate CLA in

aqueous formulations because the sodium or potassium salts of CLA are water-soluble and non-toxic as suggested by Pariza et al. One having ordinary skill in the art would have a reasonable expectation of beneficial results such as improved absorption of CLA onto the skin.

14. Claims 16-18 and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Millis or Remmereit in view of Cho et al. (US 5,667,793).

Millis or Remmereit teach topical cosmetic compositions containing CLA as discussed above. Neither reference teaches anti-cellulite agents of the instant claims. However, Cho et al. teach that xanthine compounds such as caffeine or theophylline, are capable of improving the aesthetic appearance of the skin by distributing or reducing local fat accumulation. See col. 1, lines 30-35. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the topical cosmetic compositions of either Millis or Remmereit to include an anti-cellulite agent such as caffeine or theophylline. One having ordinary skill in the art would have been motivated to do this to obtain cosmetic composition which further improve the aesthetic appearance of the skin, especially if applied to the parts of the body affected by fatty deposits, as suggested by Cho et al.

Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 4,393,043 discloses topical compositions containing CLA; US 2001/0041708 discloses cosmetic compositions and method for combating cellulite, said compositions comprising CLA and, optionally, a xanthine; WO 00/12080 discloses diet compositions containing CLA and vanadium compound.

16. No claim is allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Lamm whose telephone number is (703) 306-4541. The examiner can normally be reached on Monday to Friday from 9 to 5.

The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Marina Lamm
Patent Examiner AU 1616
6/10/03